K080195

SECTION VI

APR 28 2008

510 (K) SUMMARY

Submitter of 510 (k):	DOCERAM Medical Ceramics GmbH Hesslingsweg 65-67 44309 Dortmund Phone: +49–231–925668-0 Telefax +49–231–925668-60 e-mail info@doceram-medical.com Web: www.doceram-medical.com
Contact person	Holger Wampers General Manager Phone: +49–231–925668-63 Telefax +49–231–925668-60 e-mail h.wampers@doceram-medical.com
Date of Summary	November 06, 2007
Trade Name	Nacera Z Nacera Z Medium
Classification name:	Porcelain Powder for clinical use
Product code	EIH
C.O.R. section	872.6660
Classification	Class II
Legally marketed equvalent device	Zerion beta
510 (k) number	K061804
Device Description	Nacera Z is a ceramic material for dental restorations. Nacera Z is composed of partially sintered yttrium oxide stabilized zirconium oxide. Nacera Z is designed for manufacturing all-ceramic dental restorations (substructures) for the sole use of particular patients. It is machined on milling centers by use of CAD/CAM techniques for design and processing.

Nacera Z is designed for dental restorations like single tooth crowns or bridgeworks. It is biocompatible, biostable, and insoluble in water.

Due to the outstanding high strength of densely sintered ceramic restorations Nacera Z enables dental technicians to design finely shaped, precise, and filigree framework.

Nacera Z is delivered as presintered white blanks, which change during final sintering and effected by minimal alterations of oxide composition to characteristic hues from white to light pearl. That offers an outstanding basis for aesthetical restorations.

All above mentioned advantages ensure safe, resistant, and effective dental restorations.

Nacera Z substructures are well suited to be veneered with suitable dental porcelains using the layering technique.

Nacera Z meets all applicable requirements of International standard ISO 6872:1999 "Dental ceramic". It meets even the the international standard 13356:1997 "Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirkonia" for biocompatible and biostable dental implants and restorations.
The partially sintered Nacera Z blanks are fabricated in two different types, distincted by their presintered density and hue, each type available as disks with different dimensions depending upon custormer's request.

Nacera Z is delivered in various shapes and dimensions in order to meet individual customer requirements. Possible shapes are: disk, cylinder, cube.

Nacera Z is available in two different types. Nacera Z and Nacera Z Medium. The differ in hue effected by slightly changed ratios of the oxides in order to meet individual customer's requirements. Both types are available in both presintered densities 3,09 g/cm³ and 3,20 g/cm³.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 28 2008

Mr. Holger Wampers
Managing Director
DOCERAM Medical Ceramics GmbH
Hesslingsweg 65-67
D-44309 Dortmund
GERMANY

Re: K080195
Trade/Device Name: Nacera Z, Nacera Z Medium
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: January 2, 2008
Received: February 19, 2008

Dear Mr. Wampers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION IV

Indications for Use

510(k) Number (if known): K080195

Device Name: Nacera Z, Nacera Z Medium

Indications for Use:

Nacera Z and Nacera Z Medium are a dental ceramic designed to be used by dental technicians to manufacture all-ceramic restorations. Nacera Z and Nacera Z medium are Yttria (Yttrium Oxide) stabilized tetragonal zirconia (Zirconia oxide) powder delivered in a partially sintered state.

Nacera Z and Nacera Z Medium is specially designed for use as framework (substructure) for dental restorations, single tooth or bridge type application at anterior and posterior locations.

It is prepared for machining by use of CAM-techniques.

The machined frameworks like dental crown and bridge works are sintered to full density.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kam Mully for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080195